

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------------------------|----------------------|---------------------|------------------|
| 10/635,707 | 08/05/2003 | W. Jean Dodds | 58034-011800 | 8325 |
| 33717 GREENBERG | 7590 12/18/200 FRAURIG LLP | 6 | · EXAMINER | |
| 2450 COLORA SANTA MONIO | DO AVENUE, SUITE | 400E | WHALEY, PABLO S | |
| SANTA MONI | CA, CA 30404 | | ART UNIT | PAPER NUMBER |
| | | | 1631 | _ |
| | | | | |
| SHORTENED STATUTORY | PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS 12/18/2006 | | PAI | PER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | Application No. | Applicant(s) | | |
|--|--|--|---|--|--|
| Office Action Summary | | 10/635,707 | DODDS, W. JEAN | | |
| | | Examiner | Art Unit | | |
| | | Pablo Whaley | 1631 | | |
| Period fo | The MAILING DATE of this communication app | ears on the cover sheet with the c | orrespondence address | | |
| A SH WHIC - Exte after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANS IN THE MAIL | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE! | I. lely filed the mailing date of this communication. D (35 U.S.C. § 133). | | |
| Status | | | | | |
| 2a) | Responsive to communication(s) filed on <u>05 Au</u> This action is FINAL . 2b)⊠ This Since this application is in condition for allowar closed in accordance with the practice under E | action is non-final. nce except for formal matters, pro | | | |
| Dispositi | ion of Claims | | | | |
| 5)□ 6)⊠ 7)□ | Claim(s) 1-39 is/are pending in the application. 4a) Of the above claim(s) 19-24 and 26-39 is/are Claim(s) is/are allowed. Claim(s) 1-18 and 25 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or | re withdrawn from consideration. | | | |
| Applicati | ion Papers | | | | |
| 10)⊠ | The specification is objected to by the Examine The drawing(s) filed on <u>05 August 2003</u> is/are: Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction to the oath or declaration is objected to by the Example 1. | a)⊠ accepted or b)□ objected t drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | ected to. See 37 CFR 1.121(d). | | |
| Priority t | ınder 35 U.S.C. § 119 | <u>.</u> | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 2) Notic | t(s) se of References Cited (PTO-892) se of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | ite | | |

Application/Control Number: 10/635,707

Art Unit: 1631

DETAILED ACTION

TELEPHONE ELECTION

During a telephone conversation with John Wahl on 11/30/06 a provisional election was made

with traverse to prosecute the invention of Group I, claims 1-18 and 25, Specie A (directed to

thyroid disease), and Specie B (directed to the titer of immunity from the disease agents).

Affirmation of this election must be made by applicant in replying to this Office action. Claims

19-24 and 33-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as

being drawn to a non-elected invention.

CLAIMS UNDER EXAMINATION

An action on the merits of Claims 1-18 and 25 follows.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement filed 4/25/2006 has been considered in full.

PRIORITY

Priority to 09/419,192 filed 10/15/1999, 09/432,851 filed 11/2/1999, and US Provisional

Application 60/403203, filed 8/12/2002 has been acknowledged.

DRAWINGS

The drawings filed 8/5/2003 are acceptable.

Page 2

OBJECTIONS

Claims 4 and 7 are objected to because of the following informalities: Claim 4 is grammatically

incorrect, and should recite "a word processing program." Claim 7 should recite "dependent."

Appropriate correction is required.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I: Claims 1-18 and 25 drawn to a method of obtaining and electronically

delivering a diagnosis of the health of an animal through a combination of computerized

data and human interpretation related to the animal, classified in class 702, subclass

019. If this Group is elected, then the below summarized three specie elections are also

required.

Group II: Claims 19-24 drawn to a system of obtaining and electronically delivering a

diagnosis of the health of an animal through a combination of computerized data and

human interpretation related to the animal, classified in class 702, subclass 019. If this

Group is elected, then the below summarized three specie elections are also required.

Group III: Claims 26-39 drawn to a method of obtaining and electronically delivering an

assessment of the thyroid function of an animal through a combination of computerized

data and human interpretation related to the animal, classified in class 702, subclass

019. If this Group is elected, then the below summarized three specie elections are also

required.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups [I and III] and Group II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the system of Group II can be used to practice a materially different process, such as determining the disease status of human patients with cancer.

The inventions of Group I and Group III are related, however, they consist of distinct steps and therefore have different modes of operation, different functions, or different effects. In the instant case the inventions of Groups I and III have different functions. Group I is drawn to a method of obtaining and electronically delivering a diagnosis of the health of an animal, whereas Group III is drawn to a method of obtaining and electronically delivering an assessment of the thyroid function of an animal. Critical limitations of Group II that are separate and distinct from Group I include securing a blood sample from the animal for laboratory analysis of the total T4, total T3, free T4, free T3, T4 and T3 auto-antibodies, thyroglobulin autoantibody, and endogenous TSH.

Thus, the search for these groups together would present an undue search burden as they are directed to methods of diagnosis of health in an animal and thyroid function assessment in an animal that are generally distinct and separate.

SPECIE ELECTION REQUIREMENT

This application contains claims directed to patentably distinct and divergent species of

the claimed inventions. The applicant is further required to make the following TWO specie

elections for purposes of examination:

Specie A:

Species of disease states are recited cited in claims 8 and 17, each which are generally

separately classified and published, and thus document undue search burden if searched

together. Thus applicants are required to select ONE type disease state from claims 8 and 17.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on

the merits to which the claims shall be restricted if no generic claim is finally held to be

allowable. Currently, claim 1 and 14 are generic to the above species.

Specie B:

Species of immunity from infectious disease states are recited cited in claims 9 and 18, each of

which is directed to distinct immunological attributes which are generally separately classified

and published, and thus document undue search burden if searched together. Thus applicants

are required to select ONE type immunity state from claims 9 and 18.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 and 14 are generic to the above species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention.

Claims 1 and 10 recite "through a network, selectively an internet network." A broad

range or limitation together with a narrow range or limitation that falls within the broad range or

limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly

set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). In

the present instance, Claims 1 and 10 recite the broad recitation "network", and the claims also

recite "internet network" which is the narrower statement of the range/limitation. Correction is

required.

Claims 2 and 11 recite the limitation "report is reporting." It is unclear in what way a

report can be "reporting." Clarification as to what exactly is reported (e.g. the report itself or

something else) is requested.

Claims 3 and 12 recite the limitation "a utility." As the specification does not define or

fully and completely describe said "utility" for carrying out the intended function, it is unclear as

to the metes and bounds intended by applicant. Clarification is requested. The Examiner has

interpreted this limitation broadly for purposes of applying prior art.

Claims 4 and 13 recite the limitation "a toolbar supplementing an application." It is unclear as to the meaning of a toolbar "supplementing" an application. Does the toolbar function to select applications or something else? Clarification is requested.

Claims 5 and 14 recite the limitation "tool bar." As parent claims 1 and 10 recite a "menu on a computer screen" and is silent to the term "tool bar," it is unclear in what way the methods of claims 1 and 10 are further limited by recitation of a toolbar. Clarification is requested.

Claim 7 recites the limitation "wherein icons are grouped...for characteristics dependant on animal grouping." As parent claim 1 does not recite a step directed to "animal grouping," it is unclear whether applicant intends for "grouping" to be a method step or a limitation of the tool bar recited in parent claim 1. Clarification is requested.

Claims 9 and 18 recite the limitation "the titer of immunity from the disease agents" and "the disease." There is lack of antecedent basis for these limitations. It is noted that claims 8 and 17 recite "disease states." Correction is requested. Furthermore, it is unclear whether the "titer of immunity from the disease agents" is intended to be drug resistance, drugs better suited to treat certain disorders, disease immunity, or otherwise. The Examiner has interpreted this limitation broadly for purposes of applying prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-18 and 25 are rejected under 35 U.S.C. 103(a) as being made obvious by Barnhill et al. (US Pat. 6,248,063; Filed Dec. 22, 1997), in view of Mayaud et al. (US Pat. 5,845,255; Issued: Dec. 1, 1998) and Jensen et al. (J. Comp. Path., 1996, Vol. 114, p.339-346).

Barnhill et al. teach methods for diagnosing, screening or prognosing diseases in humans or animals [Abstract], as in claims 1, 10, and 25. The invention includes a system to receive patient data transmitted from data transmitting stations, to process these data through networks to produce a diagnostic value or prognostic value (i.e. reporting analysis), and to transmit these values to a remote data receiving means (i.e. satellite facility) [Col. 1, lines 15-35]. More specifically, Barnhill et al. teach the following aspects of the instantly claimed invention:

- Obtaining biological and physical data patient data [Col. 7, lines 40-50] (i.e. data obtained from physical inspection), as in claims 1, 10, and 25.
- Biological fluid (i.e. blood) first collected from a patient [Col. 15, lines 5-15] and clinical analysis of blood samples [Col. 20, lines 29-30], as in claims 1, 10, and 25.
- Obtaining integrated reports of computer generated data [Fig. 10], as in claims 1, 10, and 25.
- Reporting analysis indicative of a diagnosis (i.e. report) and electronically transmitting the information to a remotely located clinician's office through a network [Col. 7, lines 20-30] and [Fig. 15], as in claims 1, 3, 10, 12, and 25.
- A first computer program/system linked to a second computer program/system, communication software (i.e. word processors), and transfer of electronic data between computers using a network [Fig. 15], as in instant claims 2, 3, and 11.

Barnhill et al. do not specifically teach "drop-down menus" or "tool bars", as in claims 1, 2, 4-9, 10, 11, and 13-18. Barnhill et al. do not specifically teach "supplemental reports" or "enhanced" reports as in instant claims 1, 2, 10, and 25. Furthermore, Barnhill et al. do not specifically teach thyroid disease, as in claims 8 and 17. However, Barnhill et al. do suggest that their system could be used for diagnosis of any disease [Col. 7, lines 34-35].

Page 10

Mayaud et al. generally teach a wireless electronic prescription and remote data retrieval system for physician use [Abstract]. Mayaud et al. teach the following limitations of the instantly claimed invention:

- Drop down menus for obtaining a diagnostic report (i.e. supplemental report) [Fig. 3, 5, and 8] and further entry of drug data by a physician to create an updated physicians list (i.e. enhanced report) [Fig. 8, 15, and Fig. 21], as in claims 1, 2, 4-9, 10, 11, and 13-18.
- Predetermined supplemental report characteristics (i.e. problems associated with various disorders) [Fig. 14], as in claims 5 and 14.
- Icons grouped for name, age, and gender [Fig. 2] and disease states [Fig. 6 and 10], as
 in claims 6, 7, 15, and 16.
- Customizable tools bar with email communication [Col. 12, lines 18-25], as in claims 3 and 12.
- Drop down menus that "supplement" word processing applications (i.e. text is pre-typed)
 [Fig. 10], as in claims 4 and 13.
- Icons comprising drug concentrations and drugs better suited to teach specific disorders [Fig. 3 and 11] and methods for analyzing patient-drug interactions [Ref. Claim 31], which is a teaching for "immunity for disease agents" in claims 9 and 18.
- Toolbars whereby physicians can add new conditions to the system [Fig. 13], which further motivates the addition of new disorders and related treatments to menu bars.

Jensen et al. teach immunoradiometric assays for evaluating dogs with thyroid disease [Abstract]. Jensen et al. teach data sets represented in columns and grouped by clinical description, breed, sex, age, and TSH concentration levels (i.e. titer of immunity) [Table 1], as in claims 8, 9, 17, and 18.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the electronic prescription system of Mayaud et al. and thyroid disease data sets taught by Jensen et al. with the computer assisted diagnosis system and apparatus taught by Barnhill et al., where the motivation would have been to improve thyroid disease evaluation in animals by using a sophisticated diagnostic and electronic prescription system [Barnhill et al., Col. 7, lines 25-30]. One of ordinary skill in the art would have had a reasonable expectation of successfully using the system of Mayaud et al. and data sets of Jensen et al. with the diagnostic system of Barnhill et al. as both Mayaud et al. and Barnhill et al. teach adaptable computer-based systems that enable remote data retrieval.

Provisional Obviousness-Type Double Patenting Rejection

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1-18 and 25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 and 25 of copending Application No. 10/932,504. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the broadly encompassing scope of the instantly claimed invention causing the inventions to have overlapping embodiments. The instant claims and those of '504 recite the same method steps, with minor variations. For example, Claims 1, 6, 11, and 16 of co-pending Application '504 recite "menus on a computer screen," whereas claims 1, 10, and 25 of Application No. 10/635,707 are directed to "drop-down menus." It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to use menus on a computer screen that include drop-down menus, since the later are a particular and well-known specie of menu which may be used on a computer screen (i.e. genus). This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

Application/Control Number: 10/635,707

Art Unit: 1631

Page 13

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner Art Unit 1631

Office: 571-272-4425

Lou'A. Claw.
Paken Ekanaher
12/8/66